

Indiana University Health LaPorte Hospital
1007 Lincolnway
LaPorte, Indiana 46350-0250

September 20, 2013

U.S. Nuclear Regulatory Commission
Radioisotopes Licensing Division
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: Sir-Spheres-Proctor information

RE: NRC Radioactive Materials License #13-15151-01

Dear Sir or Madam:

I have attached a letter from SIRTEX confirming their supervision of three SIR-Spheres Microsphere procedures. I also attached the report for the three initial observed cases. By providing this information we have completed our commitment to have the manufacturer observe a minimum of three cases. Our Authorized Use is now qualified to perform these procedures independent from the manufacturer's supervision.

If you have any questions regarding this notification, please contact me at (815) 370-6538.

Sincerely,



James C. Hatten
Radiation Safety Officer

Jch

Att: SIRTEX letter and 3 Case Reports

RECEIVED SEP 26 2013



SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 105US03

September 19, 2013

Dr Syed Ali
1007 Lincolnway
La Porte IN 46350

Dear Dr Ali,

Re: SIR-Spheres® Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on July 18, 2013, Dr Brandon Martinez presented and discussed in detail the preparation and procedures associated with the treatment of patients with SIR-Spheres yttrium-90 microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. The patients were treated with SIR-Spheres microspheres.

Dr Martinez proctored the treatments and I am pleased to inform you that Dr Martinez considers that you and your staff are now trained in the preparation and the clinical aspects of treating patients with SIR-Spheres microspheres.

This letter also certifies that you were proctored for at least 3 cases by a Sirtex certified proctor in the use of SIR-Spheres® microspheres.

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC)** Program.

Yours sincerely,

cc: <Account Manager>
TEC@sirtex.com



Indiana University Health

REPORT ON SURGERY/PROCEDURE OBSERVED

THIS FORM MUST BE COMPLETED IN ITS ENTIRETY
BY THE PRECEPTING PHYSICIAN AND RETURNED TO MEDICAL STAFF SERVICES

DATE 7/18/13

NAME OF OPERATING PHYSICIAN Syed, Ali, MD

NAME OF PROCTOR Brandon Martinez, MD

NAME OF PATIENT [REDACTED] MR #

PROCTORED PROCEDURE Sir-Spheres Y-90

SCHEDULED X URGENT EMERGENCY

PROCEDURE BEGAN on time PROCEDURE ENDED

BLOOD LOSS minimal COMPLICATIONS none

MORBIDITY None

SURGICAL JUDGMENT Good

TECHNICAL ABILITY Good

OTHER COMMENTS Comp's the technical and

methodology concepts. Appropriately addressed all aspects

[Signature]
Signature of Proctoring Physician



Indiana University Health

REPORT ON SURGERY/PROCEDURE OBSERVED

THIS FORM MUST BE COMPLETED IN ITS ENTIRETY
BY THE PRECEPTING PHYSICIAN AND RETURNED TO MEDICAL STAFF SERVICES

DATE 7/17/13

NAME OF OPERATING PHYSICIAN Syed, Ali, MD

NAME OF PROCTOR Brandon Martinez, MD

NAME OF PATIENT [REDACTED] MR # [REDACTED]

PROCTORED PROCEDURE Sir-Spheres Y-90

SCHEDULED X URGENT EMERGENCY

PROCEDURE BEGAN on time PROCEDURE ENDED

BLOOD LOSS minimal COMPLICATIONS None

MORBIDITY None

SURGICAL JUDGMENT Good

TECHNICAL ABILITY Good

OTHER COMMENTS reviewed through case well understood

anatomy and potential pitfalls

[Signature]
Signature of Proctoring Physician



Indiana University Health

REPORT ON SURGERY/PROCEDURE OBSERVED

THIS FORM MUST BE COMPLETED IN ITS ENTIRETY
BY THE PRECEPTING PHYSICIAN AND RETURNED TO MEDICAL STAFF SERVICES

DATE 7/3/13

NAME OF OPERATING PHYSICIAN Sxd Ali, MD

NAME OF PROCTOR Mike Bosley

NAME OF PATIENT [REDACTED] MR # 276563

PROCTORED PROCEDURE Y90 Mapping Procedure

SCHEDULED 7/3/13 URGENT _____ EMERGENCY _____

PROCEDURE BEGAN 7/3/13 PROCEDURE ENDED _____

BLOOD LOSS 0 COMPLICATIONS _____

MORBIDITY Metastatic HCC

SURGICAL JUDGMENT Good

TECHNICAL ABILITY Good

OTHER COMMENTS well prepared

[Signature]
Signature of Proctoring Physician

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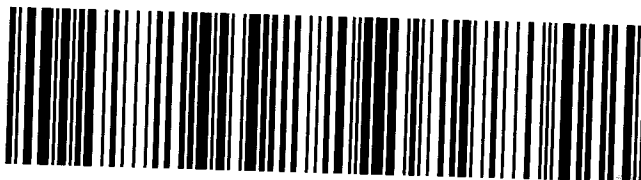
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SHIP TO: Materials Licensing Branch
U.s. Nuclear Regulatory Commission, Reg
2443 Warrenville Road, STE 210
Lisle IL 60532-4352



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